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SPC MANUFACTURING AND STOCKPILING WAIVER

An Introduction

Dr. Marco Stief, LL.M. (University of Chicago)

SPC MANUFACTURING WAIVER AGENDA

1. Executive Summary
2. Scope of the Waiver
3. Notification Obligations
4. Documentation Obligations
5. Labeling Obligations
6. Open Questions re: Interpretation
7. Wrap-up

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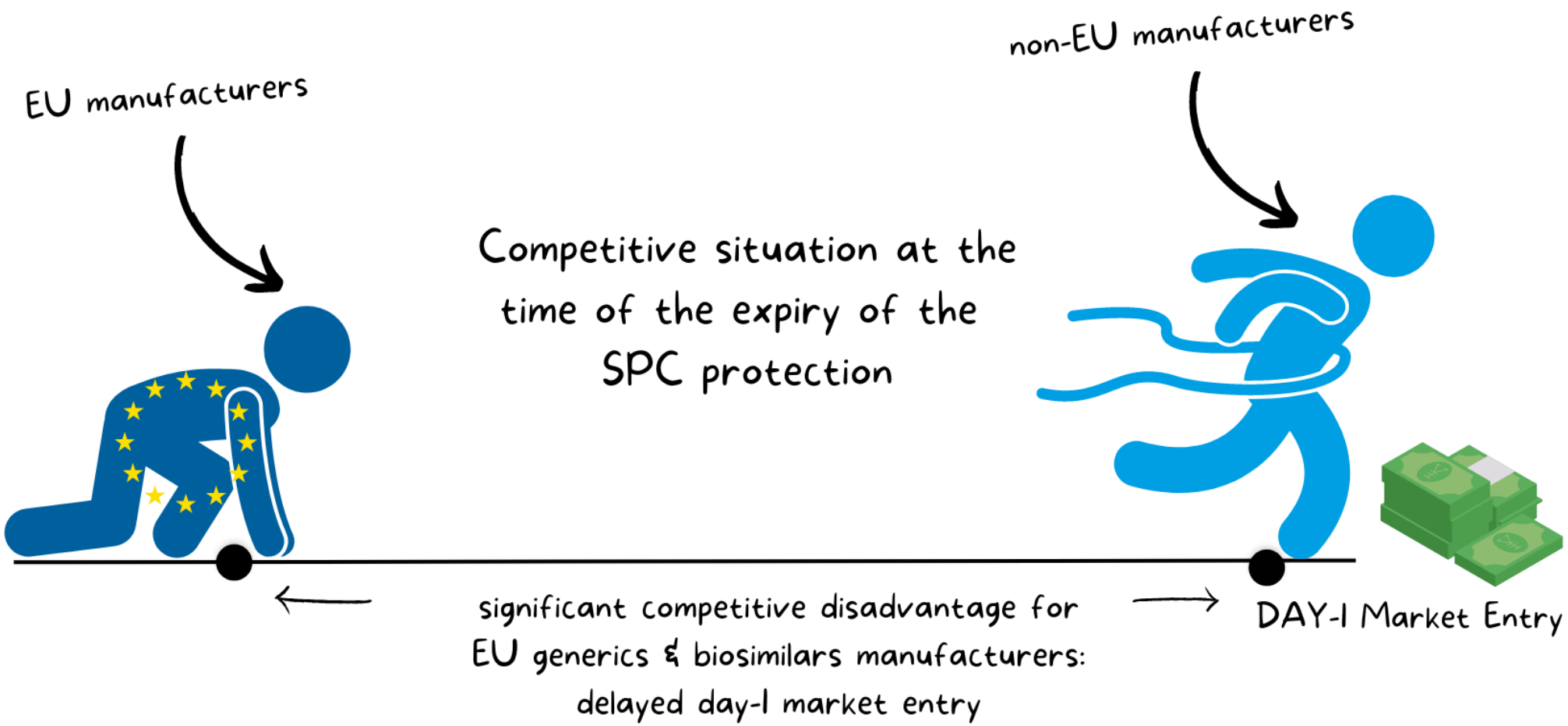
EXECUTIVE SUMMARY

THE PROBLEM


EU manufacturers
non-EU manufacturers
Competitive situation at the time of the expiry of the SPC protection
significant competitive disadvantage for EU generics & biosimilars manufacturers: delayed day-1 market entry
DAY-1 Market Entry

THE SCOPE OF THE WAIVER

Regulation (EU) 2019/933

privileged acts

Manufacturing Waiver

"Making" of a medicinal product for the purpose of export to third countries (where no protection exists)

Stockpilling Waiver

"Making" no earlier than 6 months before the expiry of the SPC for Day-1 EU-market entry

Related Acts

which are strictly necessary for such making and which would require the consent of the SPC owner: e.g. possessing; offering to supply; supplying; importing; using or synthesizing an active ingredient

BUT: Far reaching notification, documentation and labelling obligations for the "maker" !

PREVIOUS LEGAL REGIME

Phase	Activity under SPC protection	Allowed?	Legal Basis
Pre approval	Research	✓	Research exemption
	Manufacturing for purposes of obtaining a MA	✓	Bolar exemption
	Stability, BE, clinical studies etc. for approval	✓	
	Preparation and submission of a generic dossier	✓	
Post approval	Production of goods incl. related acts for export into non-EU countries with no patent/SPC-protection	⊘	SPC Regulation (EC) No 469/2009
	Production and storing of goods incl. related acts for a day-1-launch within the EU („stockpiling“)	⊘	SPC Regulation (EC) No 469/2009

CURRENT LEGAL REGIME

Phase	Activity under SPC protection	Allowed?	Legal Basis
Pre approval	Research	✓	Research exemption
	Manufacturing for purposes of obtaining a MA	✓	Bolar exemption
	Stability, BE, clinical studies etc. for approval	✓	
	Preparation and submission of a generic dossier	✓	
Post approval	Production of goods incl. related acts for export into non-EU countries with no patent/SPC-protection	✓	Manufacturing Waiver Art. 5 (2) (a) (i) (ii)
	Production and storing of goods incl. related acts for a day-1-launch within the EU („stockpiling“)	✓ 6 months	Stockpiling Waiver Art. 5 (2) (a) (iii) (iv)

WARM-UP


€9.5 billion additional net sales
for the EU pharmaceutical industry
& €254.3 million of EU API

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SCOPE OF THE SPC WAIVER

SCOPE OF THE SPC WAIVER (1)

SPC Manufacturing Waiver for export outside the EU **Art. 5 (2) (a) (i) (ii)**

privileges the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or any related act that is strictly necessary for the making, in the Union, or for the actual export;"

Stockpiling Waiver for day-1 entry in the EU **Art. 5 (2) (a) (iii) (iv)**

privileges the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or any related act thereto.

SCOPE OF THE SPC WAIVER (2)

Maker means

- The person established in the Union
- On whose behalf
- Making of a product or making of a medicinal product
- For the purpose of export to third countries, occurs.

Product means the active ingredient or combination of active ingredients of a medicinal product.

Medicinal product means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals

SCOPE OF THE SPC WAIVER (3)

Related acts Art. 5 (2) (a) (ii) (iv)

means any act in the Union, which is strictly necessary for the making or the actual export/storing if such act would otherwise require the consent of a certificate holder.

Recital 9: Strictly necessary **related acts** include (non-exhaustive list)

- Possessing, supplying, offering to supply, importing, using or synthesising an active ingredient for the purpose of making a medicinal product containing that product.
- Temporary storing or advertising for the exclusive purpose of exporting to third-country destinations.
- Related acts performed by third parties who are in a contractual relationship with the maker.

SCOPE OF THE SPC WAIVER (4)

Recital 11: acts **not covered** (numerus clausus) by the exemption

- Placing a product or a medicinal product containing that product on the market of a Member State, which is made for the purpose of export to third countries.
- Storing a product or a medicinal product containing that product with a view to EU day-one entry on the market of a Member State where a certificate is in force, either directly or indirectly after export.
- Re-importation of such a product or a medicinal product containing that product into the market of a Member State in which a certificate is in force.
- Any act or activity for the purpose of import of products or medicinal products containing those products into the Union merely for the purposes of repackaging and re-exporting.
- Any storage of products or medicinal products containing those products for any purposes other than those set out in the Regulation.

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NOTIFICATION OBLIGATIONS

NOTIFICATION OBLIGATIONS (1)

In order to invoke the SPC Manufacturing Waiver, the maker needs to comply with several notification obligations towards the SPC holder and the responsible authorities. Such notifications have to be given

no later than 3 months before the start date of the making in that Member State,

or

no later than 3 months before the first related act, prior to that making (…),

whichever is the earlier.

NOTIFICATION OBLIGATIONS (1)

Pursuant to Art. 5 (5) the following information shall be given by the maker (Annex Ia of the Regulation provides for a template). Such information will be published in the patent register:

(a) the name and address of the maker;

(b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

(c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

(d) the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; and

(e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

NOTIFICATION OBLIGATIONS (2)

Recital 14: “The information should be updated as and when appropriate.”

Recital 15: The information communicated to the certificate holder must be limited to what is “necessary and appropriate” for the SPC holder to assess if its rights are respected, and “should not include confidential or commercially sensitive information”

Criticism:

- none of the exceptions that have been recognized for third parties (unrelated to the patentee) require any communication to the patent office from the benefited party
- No link between the patent holder and the person who benefits from the application of an exception
- Notification obligations towards a competitor = significant competitive disadvantage

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DOCUMENTATION OBLIGATIONS

DOCUMENTATION OBLIGATIONS

- Any third-party in a contractual relationship with the maker who performs acts that are to be privileged needs to be fully informed and aware that such acts are subject to the Manufacturing Waiver and that any placing on the market, import or re-import of the product, or the medicinal product containing that product could infringe the SPC where, and for as long as, that certificate applies.
- The obligation of information established in the Regulation is aimed at informing those within the supply chain of the maker or downstream.
- Maker has documentation obligation in this respect *"through appropriate and documented means"*
- Risk of non-compliance: Recital 20, "*A maker who fails to comply with those due diligence requirements should not benefit from the exception, nor should any third party performing a related act (…)".*

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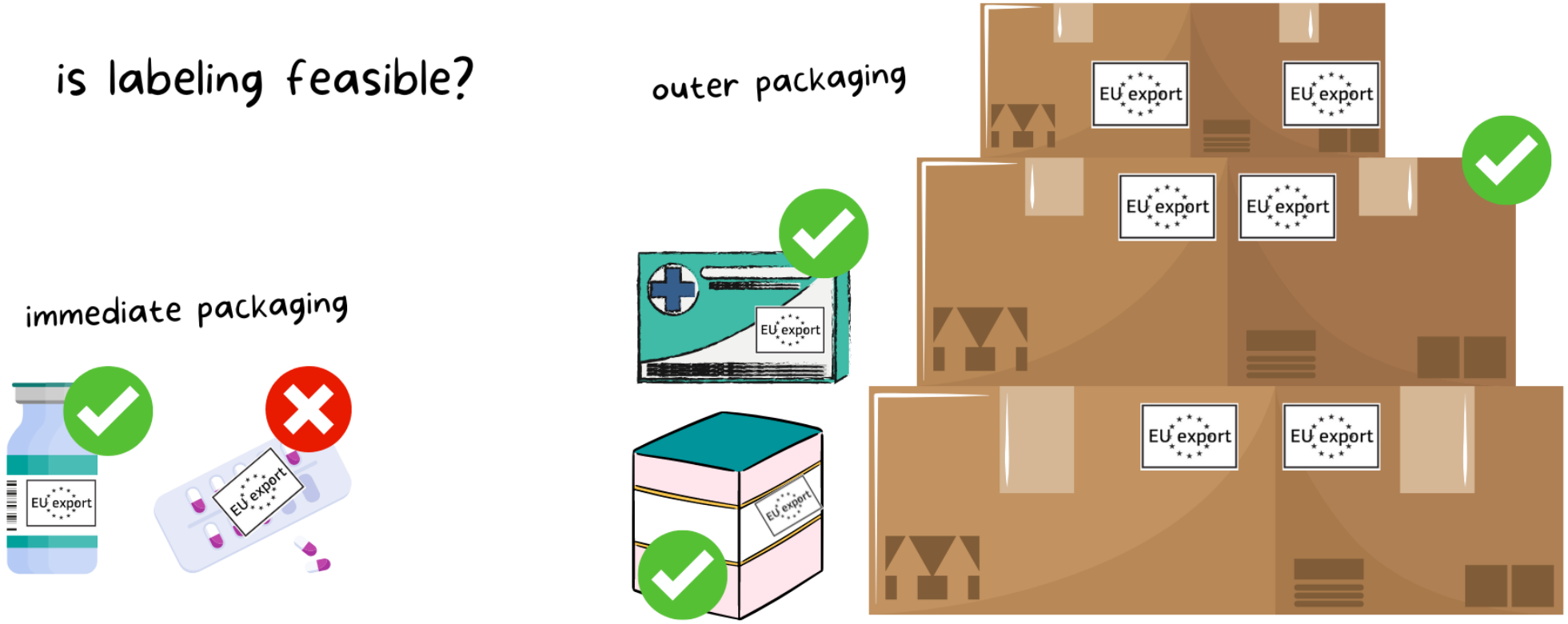
LABELING OBLIGATIONS

LABELLING OBLIGATIONS (1)

– The Regulation stipulates that the maker ensures that a logo, in the form set out in Annex-I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

– The label (Annex 1) needs to be in black and in a size as to be sufficiently visible:

LABELLING OBLIGATIONS (2)



No case law when non-feasibility will be deemed given
Risk for the maker who bears the burden of proof for non-feasibility
if only the “outer packaging” is labelled.

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OPEN QUESTIONS RE: INTERPETATION

OPEN QUESTIONS (1)

1. Applicability of the waiver also outside generic and biosimilar companies, i.e. in the originator sector?
2. Interpretation of the term "third country" with regard to the Manufacturing Waiver in Art. 5(2) lit (a) (i) ?
3. What is to be understood by the verification obligations according to Recital 18?
4. How to deal with the notification period according to Art. 5 (2) (b) if the patent is about to expire but no SPC has been applied for yet?

OPEN QUESTIONS (2)

5. Interpretation of the term "related act that is strictly necessary for the making..." according to Art. 5(2)(a)(ii) of the Regulation (?)
6. What is specifically meant by the term "any person in a contractual relationship with the maker" according to Art. 5 (9) of the Regulation?
7. How is the 6-month period of Art. 5 (2) (iii) calculated if the SPCs expire on different dates within the EU?

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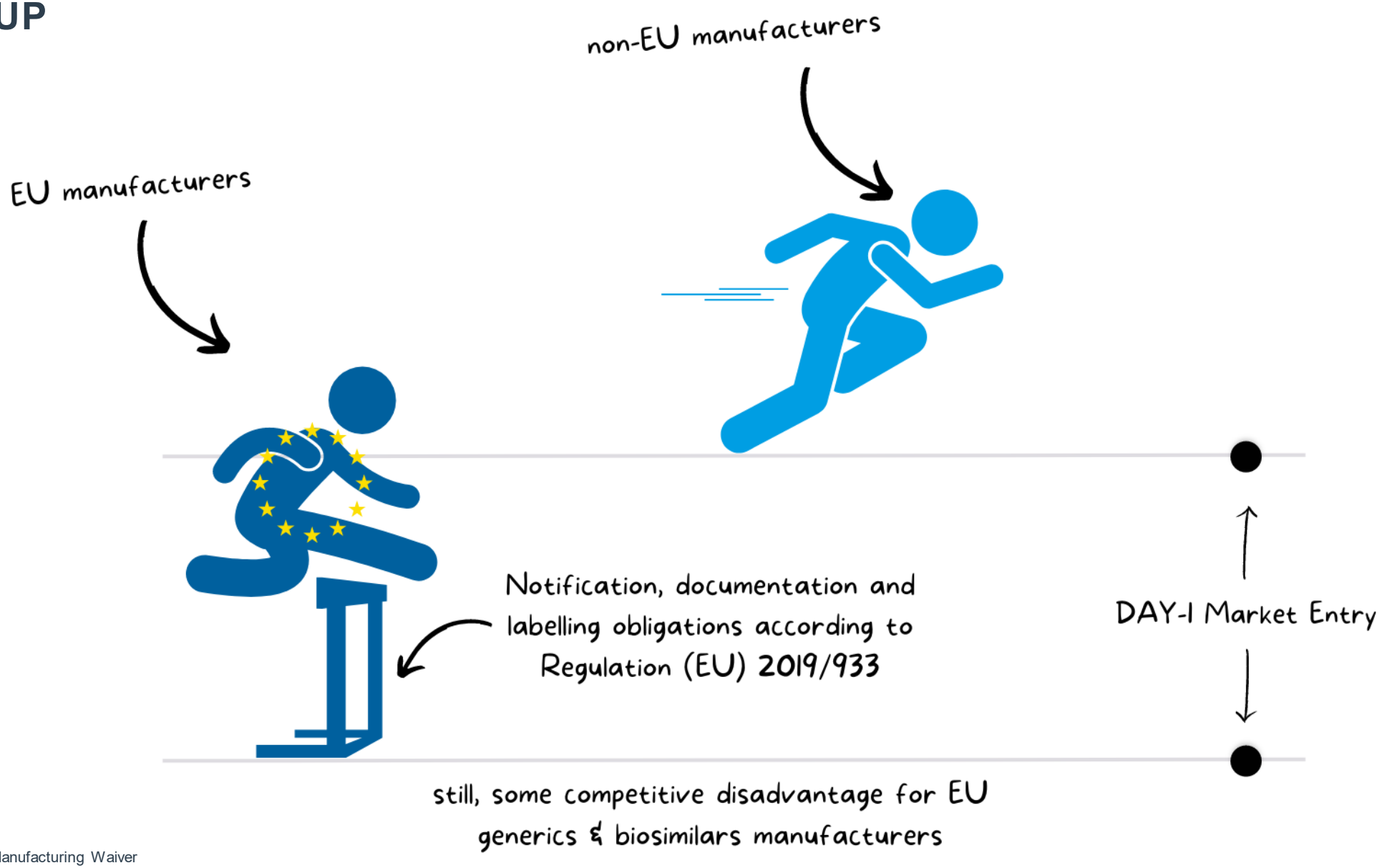
WRAP-UP

WRAP-UP


non-EU manufacturers
EU manufacturers
Notification, documentation and labelling obligations according to Regulation (EU) 2019/933
DAY-1 Market Entry
still, some competitive disadvantage for EU generics & biosimilars manufacturers

WRAP-UP

"double-edged sword"

"DELICATE BALANCING ACT"

"It will change the game a bit."

"YOU COULD PUT OUT THE FLAME WHILE IT'S STARTING BEFORE IT GOES INTO FULL BLAST".

WRAP-UP

Status Quo in Germany

– In Germany, SPC Waiver notifications have meanwhile been published for two German SPCs:

- DE 12 2007 000 056.1 for Sitagliptin; SPC owned by MSD (lapsed); waiver applied by Denk Pharma GmbH & Co. KG: https://register.dpma.de/DPMAregister/pat/register?AKZ=1220070000561
- DE 12 2008 000 068.8 for Sugammadex; SPC owned by MSD (in force); several waivers applied by Synthon B.V, Tamarang S.A., Inresa Arzneimittel GmbH and Flynn Pharma Ltd.: https://register.dpma.de/DPMAregister/pat/register?AKZ=1220080000688

– The following information will be shown in the German patent register (see e.g. Inresa Arzneimittel):

[-----] **Notification exception:**

Date of receipt: 27.10.2022

Name and address of the maker: Inresa Arzneimittel GmbH, 79114 Freiburg, DE

Type of notification: New notification

Purpose of making: Export and storing

Member State in which making is to take place: Deutschland

Number of certificate granted in the Member State of making: 12 2008 000 068.8

Member State in which first related act (if any) prior to making is to take place: Spanien

Number of certificate granted in Member State of first related act (if any) prior to making: C200900001

[-----] **Date of update of the procedure:** Nov 11, 2022

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Thank you very much for your attention!

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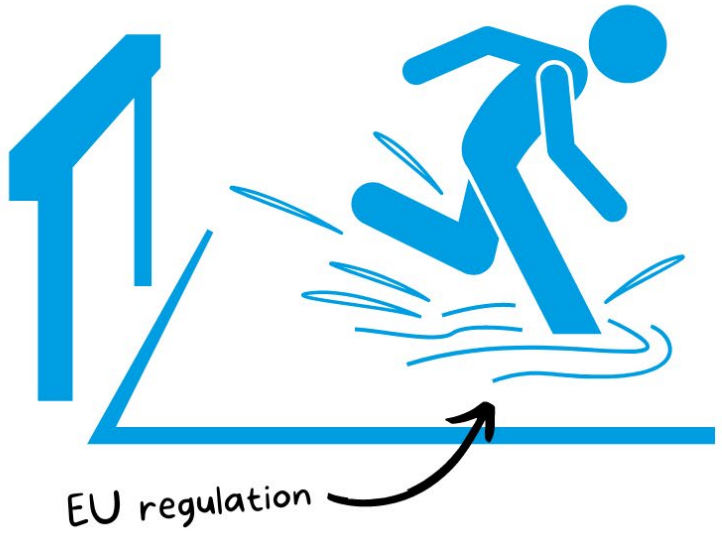
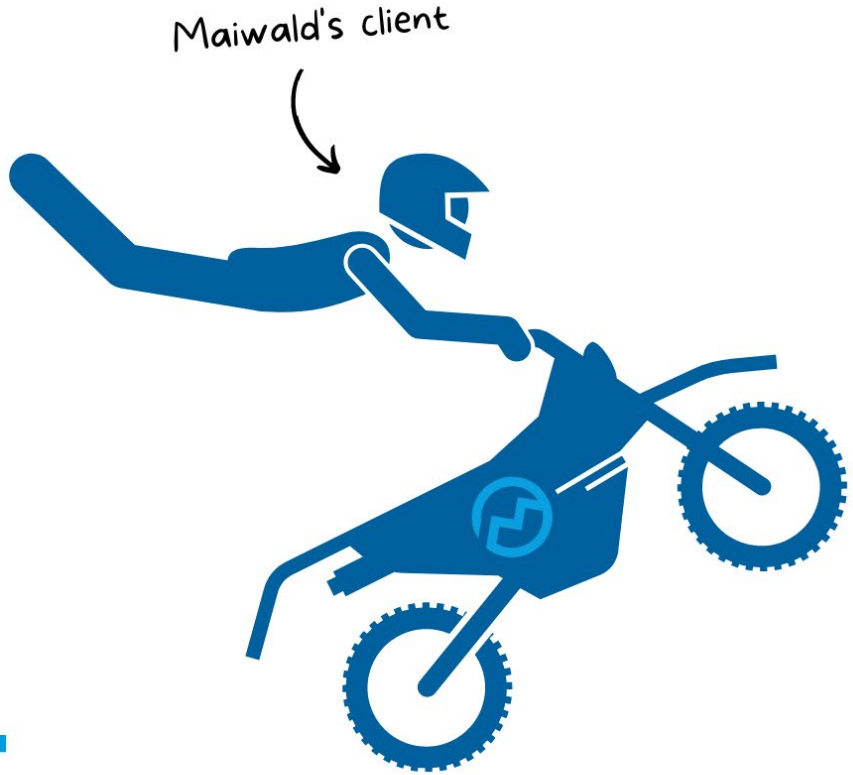
USEFUL LINKS

www.maiwald.eu/de/spc-manufacturing-waiver/

- Today‘s Presentation
- Regulation EU 2019/933
- Articles + Blogs
  - Managing IP, *Risk of SPC waiver countrerattacks makes generics extra cautious*
  - Kluwer Patent Blog, *Analysing the use of the SPC waiver provisions and its reach outside the EU*
  - IIC 2019, 971 *Analysis of the SPC Waiver Regulation* by Vidal-Quadras

Q&A





Dr. Marco Stief, LL.M. (University of Chicago)

Marco Stief is a managing partner and head of legal at Maiwald. He is an internationally recognized expert in the field of intellectual property with more than 20-year experience in IP law, in particular patent law and patent litigation.

He regularly advises companies on complex IP transactions as well as on a wide variety of technology-related contractual matters. Prior to joining Maiwald, Marco worked as an attorney-at-law at the law firms Clifford Chance, and Freshfields and as Director Legal for the Fresenius Group.

Marco teaches intellectual property law at the TU Dresden, patent law and international contract law at the University of Marburg and regularly gives lectures at TUM. He is the author of numerous expert papers and co-author of the Handbook of Patent Law published in both German and English. He is co-author and editor of the German "Handbook of Pharmaceutical Contracts" and the European handbook "Supplementary Protection Certificates".

For several years now, Intellectual Asset Management (IAM) has listed Marco among the top 300 "World's Leading IP Strategists" and among the top 1000 "World's Leading Patent Professionals".

The German JUVE Handbook cites him as one of Germany's eight leading patent litigators under the age of 50, mentioning in particular clients' appreciation for his pragmatic approach. In 2018, Who's Who Legal included Marco in the circle of the six best patent litigators in Germany, and in 2020, 2021 and 2022 identified him as a Legal Thought Leader. The German WirtschaftsWoche magazine praises him as one of the best IP lawyers in Germany and the best lawyer in the field of healthcare in the State of Bavaria. Legal500 recommends him as "pragmatic, fast, results-oriented and always meeting the highest professional standards".

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